UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/893,346	06/28/2001	Wayne D. Comper	48643-015	2638

7590 06/03/2004

MCDERMOTT, WILL & EMERY
600 13th Street, N.W.
Washington, DC 20005-3096

EXAMINER	
CHEN, STACY BROWN	
ART UNIT	**PAPER NUMBER**
1648	

DATE MAILED: 06/03/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/893,346	COMPER, WAYNE D.	
	Examiner	Art Unit	
	Stacy B Chen	1648	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *18 March 2004*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-5,7-14,16-18 and 20-24* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-5,7-14,16,17 and 20-24* is/are rejected.

7)☒ Claim(s) *2* is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *18 September 2001* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date *October 23, 2003*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

1. Applicant's amendment filed March 18, 2004 is acknowledged and entered. Claims 1-5, 7-14, 16-18 and 20-24 are pending and examined. The finality of the previous Office Action mailed November 5, 2003 is withdrawn in view of the following new grounds of rejection. Any inconvenience is regretted.

2. The rejection of claims 1-5, 7, 13-14, 16-17, 20, 21 and 23 under 35 U.S.C. 112, first paragraph, is withdrawn in view of Applicant's persuasive arguments of record.

Claim Objections

3. Claim 2 is objected to for containing multiple typos at the following locations:

- Line 9, "nephrolithiasis" has extra markings at the end of the word that do not belong.
- Line 15, "AIDS" has a dash mark in front of the term.
- Line 18, "gout" is followed by a closed-parentheses mark which does not seem to correlate with another open-parentheses mark.
- Third to last line, the acronym COPD should be spelled out.
- Next to last line, hypoxia is misspelled.

Claim Rejections - 35 USC § 112

4. Claims 2, 13, 14, 18 and 24 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

- Claim 2 is drawn to a method of for assessing therapeutic effectiveness of a treatment agent for a renal disease and/or renal complication of a disease or condition. It is unclear how surgery qualifies as a disease or condition.

- Claim 2, the term "drug abuse" is relative since there is no clear distinction, for example, between a person using drugs for a medical condition and a person using drugs for a perceived medical condition that does not actually exist.
- Claim 2, the sixth line from the bottom of claim 2 recites "lymphoreticular", but fails to indicate the rest of the disease/condition.
- Claim 13 and dependent claim 14 recite in step (i), detecting the native protein amount by conventional antibody assay. The term "conventional" is relative and lacks comparative basis.
- Claim 18, how are "specific albumen dyes" any different than non-specific albumen dyes? If there is a difference, the claim should indicate what types of albumin they are specific for.
- Claim 24, "early stage" is a relative term that lacks comparative basis and fails to indicate markers (protein amounts) that indicate an early stage. It is suggested that the term be removed and replaced with language that sets forth protein amounts, for example.

Claim Rejections - 35 USC § 102

5. Claims 1-5, 7-14, 16-17 and 20-23 are rejected under 35 U.S.C. 102(b) as anticipated by Trevisan *et al.*, of record. The Trevisan reference was previously used in a rejection and withdrawn. However, upon further consideration, the Trevisan reference is now applied.

The claims are drawn to a method for treating a person with renal disease/complications comprising administration of an agent, assaying a body fluid sample for presence, absence or decreasing amount of a particular protein over time. The assay indicates whether or not the

agent is therapeutically effective. The renal disease/complication can be selected from a host of commonly known conditions selected from claim 2. The treatment agents are lysosome-activating compounds such as ACE inhibitors (ramipril). The protein assayed for can be any protein from claim 7. Claims 16-17 are drawn to limitations wherein the assaying is by chromatography (HPLC).

Trevisan discloses the effect of low-dose ramipril on microalbuminuria in type-2 diabetic patients over a period of six months (abstract). Urinary albumin concentrations were measured by radioimmunoassay. Glycosylated hemoglobin concentrations were determined via HPLC (page 877, col. 2, last paragraph). The prior art teaches that albumin and other proteins can be detected by RIA and HPLC. Applicant's intact modified albumin has been modified biochemically with respect to native protein either by minor enzyme mediated modification or addition to its basic structure, and/or physically through a change in its three dimensional structure so that it escapes detection by conventional means. Applicant points out that a commercially available antibody may be specific for a particular epitope on a native protein that is no longer present on the intact modified form of the protein. However, if an intact modified form of the protein was modified in such a way that it escaped detection by one type of antibody, it does not necessarily follow that the intact modified form will not be detected by another conventional antibody. In other words, if the commercially available antibody detects an epitope on the intact modified form of the protein that remains after modification, the intact modified form of the protein would have been detected by the "conventional" antibody even though it actually was intact modified protein. One would not realize that an intact modified protein had been detected, although such a protein was in fact detected. Trevisan would have inherently

detected both forms of albumin: native and modified intact albumin. Therefore, lacking method steps that indicate how intact modified protein is detected apart from native protein, the claims are anticipated by Trevisan.

Claim Rejections - 35 USC § 103

6. Claims 18 and 24 are rejected under 35 U.S.C. 103(a) as being unpatentable over Trevisan in view of Jain *et al.* (4,330,296) and Suzuki *et al.* (5,246,835), all of record. The claims are drawn to a method for treating a person with renal disease/complications comprising administration of an agent, assaying a body fluid sample for presence, absence or decreasing amount of a particular protein over time. The assay indicates whether or not the agent is therapeutically effective. Albumin can be detected with specific albumin dyes. Early stage of a disease can be diagnosed when modified albumin is present in increasing amounts over time. (The teachings of Trevisan are summarized above.)

Trevisan is silent on:

- Detection of albumin with specific albumin dyes.
  - However, the detection of albumin with specific dyes is a common method of detecting albumin as evidenced by Jain *et al.* Jain teaches that dye-binding methods for measuring albumin are known. It would have been obvious to substitute of dye of Jain for the method of detecting albumin taught by Trevisan. One would have been motivated to use the dye for assaying albumin from Trevisan's method and had a reasonable expectation of success that the dye would work because Jain teaches that methods for measuring albumin with dyes are known.

- Detection of early stage disease by assaying for modified forms of albumin.
  - However, Suzuki discloses that detection of urinary microalbumin indicates early stage nephropathy (col. 1, lines 50-52). It would have been obvious to detect early-stage renal disease with Trevisan's method because Trevisan also measures microalbumin. One would have been motivated to diagnose early-stage disease and had a reasonable expectation of success because with a known method of measuring microalbumin (as evidenced by Suzuki) and that it would work because Trevisan measures microalbumin.

Therefore, the invention would have been *prima facie* obvious to one of ordinary skill in the art at the time the invention was made.

Conclusion

7. No claim is allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Stacy B. Chen whose telephone number is 571-272-0896. The examiner can normally be reached on M-F (7:00-4:30).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, James C. Housel can be reached on 571-272-0902. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

SBC

Stacy B. Chen
May 21, 2004

James C. Housel 6/1/04

JAMES HOUSEL
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 1600